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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/651,828 | 08/28/2003 | Sergei Zolotukhin | 5853-251 | 9126 |
| 7590 | 06/14/2006 | | EXAMINER | |
| Akerman Senterfitt Suite 400 222 Lakeview Avenue West Palm Beach, FL 33402-3188 | | | GUZO, DAVID | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1636 | |

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|-------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/651,828 | ZOLOTUKHIN, SERGEI | |
| | Examiner David Guzo | Art Unit 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 29 March 2006.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 2-78 is/are pending in the application.

4a) Of the above claim(s) 58-78 is/are withdrawn from consideration.

5) Claim(s) 2-3, 19-34 and 51-57 is/are allowed.

6) Claim(s) 4-18 and 35-50 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

Detailed Action

Claims 58-78 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/9/05.

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16-18, 35-40 and 43-50 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by During et al.

This rejection is maintained for reasons of record in the previous Office Action (mailed 12/1/05) and for reasons outlined below.

Applicant traverses this rejection by canceling claim 1 and amending claim 2 to include the limitations of claim 1. It is noted that claim 2 was not rejected over During et al. because During et al. did not teach or suggest the limitation of having the nucleotide sequences encoding the AAV rep and chimeric cap proteins interposed between AAV

ITR elements. Applicant argues that During et al. fails to teach or anticipate the claimed invention wherein the invention includes the limitations of claim 2.

Applicant's arguments filed 3/29/06 have been fully considered but they are not persuasive. As a result of applicant's amendment filed 3/29/06, the rejection of claims 1, 4-9 and 12-13 over During et al. is withdrawn. However, the remaining claims previously rejected over During et al. (Claims 16-18, 35-40 and 43-50) have not been amended and applicant's arguments that they do not teach the invention, which includes limitations not recited in the claims, is not persuasive. For example, unlike amended claim 2, claims 16-18, 35-40 and 43-50 do not recite the limitation that the nucleotide sequences encoding the AAV rep and chimeric cap proteins are interposed between AAV ITR elements. Contrary to applicant's assertions, During et al. teaches a first nucleotide sequence encoding a AAV rep protein (paragraphs [0099], [0123], etc.), a second sequence encoding a chimeric cap protein comprising sequences from two different serotypes (paragraphs [0067-0068], [0099], claims 1-49, etc.), a vector comprising a transgene interposed between AAV TR (ITR) elements ([0090]-[0091]), etc. During et al. therefore teaches the claimed invention.

Claims 16-18 and 35-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Gao et al.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Applicant traverses this rejection by arguing that Gao et al. does not teach the claimed invention which applicants indicate includes the limitation that the nucleotide sequences encoding the AAV rep and chimeric cap proteins interposed between AAV ITR elements. Applicant argues that Gao et al. does not teach the chimeric capsid proteins of the claimed invention but rather that the term "chimeric" as employed by Gao et al. is applied to the entire virion and rep is fused in frame with a cap.

Applicant's arguments have been considered but are not found persuasive. As a result of applicants' amendment filed 3/29/06, the rejection of claims 1 and 4-15 over During et al. is withdrawn. However, the remaining claims (16-18 and 35-50) are still rejected over Gao et al. Contrary to applicant's assertions, Gao et al. does teach chimeric AAV capsid proteins and nucleotide sequences encoding said chimeric capsid proteins (see for example paragraphs [0075], [0091], etc.). With regard to Gao et al. not teaching a non-naturally occurring nucleic acid comprising the nucleotide sequences encoding the AAV rep and chimeric cap proteins interposed between AAV ITR elements, it is noted that claims reciting this limitation are not included in this rejection. Gao et al. teaches the limitations of the rejected claims (See for example paragraphs [0024], [0107], [0110], [0111], [0118], [0122], [0133], [0154] and [0249]). Gao et al. therefore teaches the claimed invention.

35 USC 112, 2nd Paragraph Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-15 are vague because they depend from canceled claim 1.

Miscellaneous

No status identifier was included for claim 35. Applicants must include status identifiers for all claims (See 37 CFR 1.121). Any future amendments which do not include correct status identifiers for all claims will be considered non-responsive.

Claims 2-3, 19-34 and 51-57 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
June 2, 2006


DAVID GUZO
PRIMARY EXAMINER